IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA,
STATE OF ALASKA,
STATE OF CALIFORNIA,
STATE OF COLORADO,
STATE OF CONNECTICUT,
STATE OF DELAWARE,
STATE OF FLORIDA,
STATE OF GEORGIA,
STATE OF HAWAII,
STATE OF ILLINOIS,
STATE OF INDIANA,
STATE OF LOUISIANA,
STATE OF MARYLAND,
COMMONWEALTH OF MASSACHUSETTS,
STATE OF MICHIGAN,
STATE OF MINNESOTA,
STATE OF MONTANA,
STATE OF NEVADA,
STATE OF NEW HAMPSHIRE,
STATE OF NEW JERSEY,
STATE OF NEW MEXICO,
STATE OF NEW YORK,
STATE OF NORTH CAROLINA,
STATE OF OKLAHOMA,
STATE OF RHODE ISLAND,
STATE OF TENNESSEE,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WISCONSIN, and
DISTRICT OF COLUMBIA, *ex rel.* OMNI HEALTHCARE, INC.,

Plaintiffs,

v.

OPKO HEALTH, INC. and BIOREFERENCE LABORATORIES, INC.,

Defendants.

CASE NO.: _____

COMPLAINT PURSUANT TO FEDERAL FALSE CLAIMS ACT, 31 U.S.C. § 3729 *et seq.*, AND PENDENT STATE FALSE CLAIMS ACTS

FILED *IN CAMERA* AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

NOT FOR PUBLIC DISCLOSURE
DO NOT PLACE IN PRESS BOX
DO NOT ENTER ON PACER

JURY TRIAL DEMANDED

***QUI TAM* COMPLAINT**

Relator Omni Healthcare, Inc. ("Omni" or "Relator"), on behalf of the United States, the State of Alaska, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New Hampshire, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, the State of Wisconsin and the District of Columbia (collectively "the States" or "the Plaintiff States"), brings this action for violations of the Federal False Claims Act, 31 U.S.C. §§3729 *et seq.* ("False Claims Act" or "FCA"), as well as for violations of the following state false claims acts: The Alaska Medical Assistance False Claims Reporting Act, AK Stat § 09.58.010 *et seq.*; The California False Claims Act, Cal. Gov't Code §§12650 *et seq.*; The Colorado Medicaid False Claims Act, 25.5-4-304-25.5-4-310; The Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301b; The District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 *et seq.*; The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 *et seq.*; The Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*; The Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 *et seq.*; The Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 *et seq.*; The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 *et seq.*; The Indiana False Claims and Whistleblower Protection Act, Indiana Code §5-11-5.5; The Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 *et seq.*; The Maryland False Health Claims Act of 2010, Md. Code Ann. § 2-602 *et seq.*; The Massachusetts False

Claims Act, Mass. Ann. Laws. Ch. 12, §§5A *et seq.*; The Michigan Medicaid False Claims Act, MCLS §§400.601 *et seq.*; The Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; The Montana False Claims Act, Mont. Code Anno. §§17-8-401 *et seq.*; The Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*; The New Hampshire False Claims Act, RSA tit. XII, Ch. 167: 61-b; The New Jersey False Claims Act, N.J. Stat. §2A:32C-1 *et seq.*; The New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §27-2F-4 *et seq.*; The New York False Claims Act, NY CLS St. Fin. §§187 *et seq.*; The North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-605 *et seq.*; The Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§5053 *et seq.*; The Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 *et seq.*; The Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-171 *et seq.*; The Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 *et seq.*; The Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 *et seq.;* and the Wisconsin False Claims for Medical Assistance Act[1], Wis. Stats. §§20.931 (collectively the "State False Claims Acts" or "State FCAs"), to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts. Relator also seeks to recover money on behalf of the United States and private insurance policyholders through the California Insurance Frauds Prevention Act, Ins. Code §§ 1871 *et seq*. and the Illinois Claims Fraud Prevention Act, 740 ILCS 92/1 *et seq*. for fraudulent submissions made to private insurance companies by Defendants in those states.

[1] The Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§ 20.931 *et seq*. was repealed effective July 15, 2015. Relators seek to recover for false claims submitted prior to the repeal.

INTRODUCTION

1. This is an FCA case arising from fraud against federal and state healthcare programs involving the improper billing of medically unnecessary blood tests which were not ordered by physicians. Defendants have engaged in a scheme to defraud the United States and the Plaintiff States, as well as private insurance companies in the States of California and Illinois, by knowingly submitting and/or causing to be submitted false and/or fraudulent claims for payment to Government healthcare programs, including Medicare, Medicaid, and TRICARE ("Government Payors"), and to private insurers in California and Illinois (along with Government Payors, collectively "Payors"). Specifically, Defendants' fraudulent conduct includes billing Payors for blood tests that are medically unnecessary and which are not requested by physicians.

2. Clinical laboratories generate billions of dollars per year, a large portion of which is reimbursed by Payors. While the typical laboratory claim is relatively low in cost, the sheer volume of laboratory services performed provides an opportunity for potential losses due to fraud and abuse with these services to reach the hundreds of millions of dollars. Fraud in this area can be particularly challenging to identify and investigate without the help of information brought by those in the industry, such as Relator.

3. Since at least 2012, and continuing through the present, Relator alleges Defendants have abused Payors by routinely charging for tests that were not ordered by physicians and/or were medically unnecessary. As alleged in more detail herein, physicians routinely ordered blood tests which should have been performed and billed by Defendants using CPT code 85027, when, regardless of the physicians' orders, Defendants performed a more

complex, medically unnecessary test and billed CPT code 85025 instead. The difference in the codes will be discussed in more detail below.

4. The FCA provides that any person who knowingly submits or causes to be submitted to the Government a false or fraudulent claim for payment or approval is liable for a civil penalty of $5,500 to $11,000 for each such claim submitted on or before November 2, 2015, and $10,781 to $21,563 for each such claim submitted after November 2, 2015, as well as three times the amount of the damages sustained by the Government. The FCA permits persons having information regarding a false or fraudulent claim against the Government to bring an action on behalf of the Government and to share in any recovery. The complaint must be filed under seal, without service on the defendants. The complaint remains under seal while the Government conducts an investigation of the complaint's allegations and determines whether to join the action.

5. Pursuant to the FCA and the State FCAs, Relator seeks to recover on behalf of the United States and Plaintiff States damages and civil penalties arising from Defendants' purposeful submission of false and fraudulent claims to the Government.

PARTIES

6. The United States is a plaintiff in this action. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Center for Medicare and Medicaid Services ("CMS"), which agencies administer the Medicare and Medicaid programs, as well as the Department of Defense ("DOD"), which agency administers the CHAMPUS/TRICARE program.

7. The States of Alaska, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota,

Montana, Nevada, New Jersey, New Mexico, New Hampshire, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin and the District of Columbia are plaintiffs for whom recovery is sought.

8. The United States and the Plaintiff States are collectively referred to as "Government Plaintiffs."

9. Relator Omni Healthcare, Inc. is a professional medical company based primarily in Brevard County, Florida. Relator practices in central Florida and specializes in the field of internal medicine with a subspecialty in hematology and oncology. Relator, through its principal, regularly treats cancer patients on both an inpatient and outpatient basis, and regularly purchases drugs and orders tests from various distributors and laboratories in order to treat its patients for conditions associated with cancer and attendant side effects.

10. Relator is the original source of the facts and information set forth concerning the activities of the Defendants. The facts alleged within are based upon the personal observations of Omni's principal, as well as documents and information in his possession, which were acquired in connection with his work. The information and observations led Relator to question Defendants' fraudulent actions.

11. Relator's principal, Craig Deligdish, M.D., has been a licensed Laboratory Director in the State of Florida since 1992. He founded the Melbourne Medical Laboratory, Inc., a full-service laboratory, serving physician offices, hospitals and skilled nursing facilities. In 2002, Dr. Deligdish founded the Florida Clinical Laboratory, a full-service laboratory serving skilled nursing facilities across the State of Florida. Dr. Deligdish served as the laboratory's Director until 2012. On December 31, 2012, the Florida Clinical Laboratory was sold to Defendant BioReference Laboratories, Inc. ("BRL"), and Dr. Deligdish assumed responsibility

as Medical Director of Defendant BRL's Melbourne and Jacksonville laboratories. He served in this position until 2016. Dr. Deligdish currently serves as Laboratory Director of the Melbourne Medical Laboratory and Prospira (https://www.prospirapaincare.com/), a multi-specialty physician group in Florida.

12. Defendant OPKO Health, Inc. ("OPKO") is a Delaware corporation with its principal place of business at 4400 Biscayne Boulevard in Miami, Florida. OPKO is a publicly traded company (NASDAQ: OPK), which grossed $996 million in revenue in 2018. It is a medical testing and researching company focused on diagnostics and pharmaceuticals. According to its website, OPKO currently operates throughout nine countries.

13. Defendant BioReference Laboratories, Inc. ("BRL") is a wholly-owned subsidiary of OPKO. BRL is the third-largest clinical laboratory in the United States. It offers laboratory testing services utilized by healthcare providers in the detection, diagnosis, evaluation, monitoring, and treatment of several types of diseases and conditions. BRL markets and sells its services to physician offices, clinics, hospitals, employers, and governmental units on a national scale.

JURISDICTION AND VENUE

14. This action arises under the FCA. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1345 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court for actions brought under 31 U.S.C. § 3730.

15. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a), which authorizes nationwide service of process, because Defendants can be found in, reside in, have transacted business in, and/or have committed the alleged acts in the District of Delaware.

16. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)-(c) and 31 U.S.C. § 3732(a) because all of the Defendants can be found in, reside in, and/or have transacted business in the District of Delaware, and a number of Defendants' alleged acts occurred in this District.

17. Relator knows of no other FCA complaints that have been filed against Defendants alleging the same or similar actions. Additionally, Relator is an original source as defined in 31 U.S.C. § 3730(e)(4)(B). Relator made voluntary disclosures to the United States prior to the filing of this lawsuit.

REGULATORY OVERVIEW

The False Claims Act

18. The False Claims Act, 31 U.S.C. §§ 3729 *et seq.* reflects Congress' objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345 at 1 (1986). As relevant to this case, the FCA establishes liability for an individual or entity that:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

31 U.S.C. § 3729(a)(1).

19. The FCA defines "knowing" and "knowingly" to mean that a person with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of

the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required and an innocent mistake is not a defense to an action under this act. *Id.*

20. An "obligation" within the meaning of the FCA includes "[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment." 42 C.F.R. § 401.305(b).

21. In addition to treble damages, the FCA provides for the assessment of civil penalties for each violation.

The California Insurance Frauds Prevention Act

22. California's Insurance Frauds Prevention Act, Ins. Code §§ 1871 *et seq.* ("IFPA"), allows relators to file lawsuits based on the submission of false claims to private insurance companies. IFPA allows the local district attorney or the Insurance Commissioner for the State of California to intervene in and control the lawsuit. The statute authorizes civil penalties of between $5,000 and $11,000 per fraudulent claim.

The Illinois Claims Fraud Prevention Act

23. The Illinois Claims Fraud Prevention Act, 740 ILCS 92/1 *et seq.* ("CFPA"), allows relators to file lawsuits based on the submission of false claims to private insurance companies. Rather than bringing an FCA case on behalf of the government and taxpayers, the statute allows the relator to bring the case on behalf of the government and policyholders. CFPA authorizes civil penalties of between $5,000 and $11,000 per fraudulent claim.

Government Healthcare Programs

The Medicare Program

24. In 1965, Congress enacted Title XVIII of the Social Security Act ("SSA"), known as the Medicare program, to pay for certain healthcare services provided to certain segments of the population. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq.*

25. HHS, through CMS, administers the Medicare program.

26. Part B of the Medicare program authorizes payment of federal funds for outpatient health services, including diagnostic tests. *See generally* Medicare Benefit Policy Manual at Ch. 15.

27. CMS enters into agreements with healthcare providers, such as Defendants, to establish their eligibility to participate in the Medicare program. Individuals or entities who are Medicare providers, such as Defendants, may seek reimbursement from CMS for services rendered to Medicare beneficiaries.

28. During all times relevant herein, providers authorized to participate in the Medicare program have been required to certify as follows:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . and, on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application: Clinics/Group Practices, CMS Form-855B, at 31.

29. The SSA provides: "no payment may be made under Part A or Part B [of Medicare] for any expenses incurred for items or services which . . . are not reasonable and necessary . . . ." 42 U.S.C. § 1395y(a)(1)(A).

30. The SSA defines "certificate of medically necessity" as "a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary . . . ." 42 U.S.C. § 1395m(j)(2)(B).

The Medicare Advantage Program

31. In lieu of coverage under Part A or Part B of Medicare ("Original Medicare"), eligible beneficiaries can choose to receive coverage under Medicare Advantage plans, or Part C plans.

32. Under Medicare Advantage, CMS is authorized to contract with private insurers to offer a variety of health plan options for beneficiaries, including coordinated care plans ("Medicare Advantage Plans" or "MAPs"). MAPs provide all original Medicare benefits, and most offer additional benefits as well.

33. CMS funds MAPs using a process established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Pursuant to the process, CMS pays a monthly capitation payment to each MAP for each of that plan's enrolled beneficiaries. The MAP, in turn, pays the capitation payment to the enrollee's doctor or medical practice, after retaining a percentage for administration.

The Medicaid Program

34. The Medicaid program is a health insurance program administered through HHS. Medicaid was designed to assist participating states in providing medical services, durable medical equipment, and prescription drugs to financially-needy individuals who qualify for the program.

The CHAMPUS/TRICARE Program

35. The CHAMPUS/TRICARE program is a federally-funded program that provides benefits to (a) the spouses and unmarried children of (1) active duty and retired service members and (2) reservists who were ordered to active duty for thirty (30) days or longer; (b) the unmarried spouses and children of deceased service members; and (c) retirees.

Relevant Current Procedural Terminology Codes

36. Current Procedural Terminology ("CPT") codes are numbers assigned to every task and service a medical practitioner may provide to a patient, including medical, surgical, and diagnostic services. They are used by insurers to determine the amount of reimbursement a practitioner will receive for specific services.

37. The CPT codes at issue in this complaint are:

(i) CPT Code **85025**: Blood count, complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count) **and WBC automated differential**

(ii) CPT Code **85027**: Blood count, complete (CBC), automated (Hgb, Hct, RBC, WBC and platelet count)

(emphasis added).

38. The significance of the difference in the CPT codes above will be discussed herein.

ALLEGATIONS

39. A Complete Blood Count ("CBC") is a test that measures the cells that make up an individual's blood: red blood cells, white blood cells, and platelets. Doctors generally order CBCs as part of a routine checkup, to check for anemia, to monitor blood conditions, or to see how medications or chemotherapy are affecting blood. When a physician orders a CBC with no

white blood cell ("WBC") differential, the correct CPT code for a laboratory to use for billing Payors is 85027. Physicians must specifically order a CBC with automated white blood cell differential in order for a laboratory to bill for that test, identified as CPT code 85025, which is a more expensive test.

40. Beginning on or around 2012, BRL, the nation's third-largest clinical laboratory, began routinely and purposefully running and billing for the more expensive and medically unnecessary test using CPT code 85025, even when physicians ordered the less expensive test, a CBC with no WBC differential, which should have been billed using CPT code 85027. BRL engaged in this behavior solely to receive higher reimbursements from Payors than those to which it was entitled.

41. Upon information and belief, BRL began running and billing for the more complex and medically unnecessary test (CPT code 85025) approximately 95 percent of the time beginning in 2012. The less costly and more medically-appropriate test (CPT code 85027) amounted to approximately 2 percent of the CBC services billed to Medicare by BRL.

42. BRL's definition of "CBC" effectively excluded the less costly and more medically-appropriate test—a request to run a CBC meant to run the test and to bill Payors using CPT code 85025. Test requisition forms on BRL's website, just like the paper copies provided to doctors, do not define "CBC," nor does the "Test Directory" on BRL's website provide answers about its tests.

43. When physicians select tests from BRL's requisition forms, they are given the option to select "CBC with differential platelet count 0053" or to handwrite their request on a single line near the bottom of the form, adjacent to the words "Other Tests." Other less complex blood tests are not listed. The design of the form and the failure to list the more cost effective,

medically appropriate options is part of an effort by BRL to mandate ordering of the more complex test.

44. Through personal observations and documentation received in connection with his work, Relator's principal became aware of BRL's policy to perform a "CBC with WBC differential" regardless of a physician's written order. After learning of BRL's fraudulent actions, Relator ordered 14 "CBC" labs to see how they would be handled by BRL. In every case, BRL followed its policy, disregarding the physician's order and running a "CBC with WBC differential," a medically unnecessary test—not ordered by a physician—which financially benefitted the company at the expense of taxpayers. Nine other physician lab orders for "CBC without differential" were also altered. Each time, the lab followed BRL policy, completing and billing for the unnecessary, unrequested, and more complex test. Relator's personal knowledge includes, but is not limited to, the following patient examples:

- Patient A (M.F., female, age 74): On February 6, 2019, a handwritten test request—with "CBC" circled in the "Other Test" category—was ordered; however, the more expensive test—CBC without WBC differential—was performed and the results were delivered to Relator. (*See* Exhibit A).
- Patient B (M.B., female, age 72); on March 19, 2019, a handwritten test request with "CBC" was ordered; however, the more expensive test – CBC with WBC differential – was performed and the results were delivered to Relator (*See* Exhibit B)
- Patient C (F.N., male, age 72): on February 14, 2019, a handwritten test request with "CBC" was ordered; however, the more expensive test – CBC with WBC

differential – was performed and the results were delivered to Relator. (*See* Exhibit C)

- Patient D (M.S., female, age 71): on March 19, 2019, a handwritten test request with "CBC" was ordered; however, the more expensive test – CBC with WBC differential – was performed and the results were delivered to Relators (*See* Exhibit D)
- Patient E (C.G., female, age 74): On February 14, 2019, a handwritten test request clearly orders a "CBC without differential" circled under the "Other Test" category; however, the more expensive test—CBC with WBC differential—was performed and the results were delivered to Relator. (*See* Exhibit E).
- Patient F (J.C., female, age 81): On March 11, 2019, a handwritten test request clearly orders a "CBC without differential" circled under the "Other Test" category; however, the more expensive test—CBC with WBC differential—was performed and the results were delivered to Relator. (*See* Exhibit F).
- Patient G (B.G., female, age 90): On February 18, 2019, a handwritten test request clearly orders a "CBC without differential" under the "Other Tests" category; however the more expensive test—CBC with WBC differential—was performed and the results were delivered to Relator. (*See* Exhibit G).
- Patient H (E.S., female, age 80): On March 11, 2019, a handwritten test request clearly orders a "CBC without differential" circled under the "Other Tests" category; however, the more expensive test—CBC with WBC differential—was performed and the results were delivered to Relator. (*See* Exhibit H).

45. On all of the examples above, BRL performed and provided test results for "CBC with WBC differential" (85025) when "CBC" (85027) was actually ordered.

46. Conversely, all of the tests selected using the checkbox adjacent to the description "CBC with WBC differential platelet count" (85025) were performed as ordered.

47. The leadership team at BRL began to question the practice of billing tests that were not requested and/or necessary when it was brought to their attention by an employee in the processing and ordering department. In response, the company's Chief Medical Officer and Laboratory Director stated it would be a "disservice" to the patients to perform any other test, regardless of what the physicians ordered. (*See* Exhibit I).

48. Other BRL executives outwardly stated that their practices did not run afoul of Government regulations because it was their internal policy to run a "CBC with differential" (test 0053, CPT code 85025) each time a "CBC" was requested. A company Vice President stated that as much through an email disseminated to BRL employees. (*See* Exhibit I).

49. However, as discussed above, contrary to the Vice President's statements, BRL's practices are deceptive and fraudulent. The correct coding for a form wherein the physician has simply ordered "CBC"—with no mention of a WBC differential—is CPT code 85027. Physicians must specifically order a CBC with WBC differential in order for the test to be coded and billed using CPT code 85025.

Damages

50. From 2012 through the present, Relator estimates Defendants received approximately $37.8 million in reimbursements for conducting tests for "CBC with WBC differential" (85025) from Medicare alone. The estimate includes the actual payments from the Medicare fee-for-service program from 2012 through 2017, which, in turn, were used to

extrapolate payments for 2018 and 2019, and to estimate those made to the Medicare Advantage program for the entire time period. Government statistics and Relator's experience indicate that, on average, 32 percent of these claims were fraudulent. Based on these estimates, Relator alleges Defendants caused $12.1 million in single damages to Medicare alone. This figure does not include damages to the Plaintiff States or private insurers.

COUNT I

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT
31 U.S.C. §§ 3729 *et seq.*

51. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein. This count sets forth claims for treble damages and civil penalties under the FCA.

52. As described in greater detail above, Defendants abused Government healthcare programs in connection with improper billing for medically unnecessary blood tests. More specifically, Defendants routinely billed Payors for more expensive blood tests than those that were actually ordered by physicians and/or purposefully required physicians to order the more expensive blood test when a less expensive test was available.

53. Under the FCA, Defendants have violated:

i. 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;

ii. 31 U.S.C. § 3729(a)(1)(B) by knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and

iii. 31 U.S.C. § 3729(a)(1)(G) by knowingly making, using, or causing to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the government.

54. Because of the false claims made by Defendants, the United States has suffered and continues to suffer damages, and is therefore entitled to a recovery as provided by the FCA of an amount to be determined at trial, plus a civil penalty for each violation.

COUNT II

VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT, CALIFORNIA GOVERNMENT CODE §§ 12651 *et seq.*

55. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein, including but not limited to evidence that shows Defendants violated California Business and Professions Code §650, California Welfare and Institutions Code §14107.2, and the California Code of Regulations Title 22 §51501(a).

56. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 12651(a)(1) of the Act. Such claims caused actual damages to the State.

57. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 12651(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT III

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT FOR PUBLIC ASSISTANCE PROGRAMS CONN. GEN. STAT. § 17b-301 *et seq.*

58. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

59. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 17b-301b(1) of the Act. Such claims caused actual damages to the State.

60. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 17b-301b(2) of the Act. Such claims caused actual damages to the State.

COUNT IV

VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT DEL. CODE ANN. TIT. 6, § 1201 *et seq.*

61. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

62. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 1201(a)(1) of the Act. Such claims caused actual damages to the State.

63. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 1201(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT V

VIOLATIONS OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. CODE ANN. §§ 2-308.14 *et seq.*

64. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

65. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the District of Columbia in violation of Section 308.14(a)(1) of the Act. Such claims caused actual damages to the State.

66. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 308.14(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT VI

VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT FLA. STAT. §§ 68.082(2) *et seq.*

67. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

68. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 68.082(2)(a) of the Act. Such claims caused actual damages to the State.

69. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 68.082(2)(a) of the Act. Such claims caused actual damages to the State.

COUNT VII

VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT GA. CODE ANN. §49-4-168.1 *et seq.*

70. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

71. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 49-4-168.1(a)(1) of the Act. Such claims caused actual damages to the State.

72. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 49-4-168.1(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT VIII

VIOLATIONS OF THE HAWAII FALSE CLAIMS ACT HAW. REV. STAT. §661-21 *et seq.*

73. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

74. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 661-21(a)(1) of the Act. Such claims caused actual damages to the State.

75. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 661-21(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT IX

VIOLATIONS OF THE ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT 740 ILL. COMP. STAT. ANN. §§ 175/3 *et seq.*

76. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

77. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 175/3(a)(1) of the Act. Such claims caused actual damages to the State.

78. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 175/3(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT X

VIOLATIONS OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT INDIANA CODE 5-11-5.5-2 *et seq.*

79. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

80. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 5-11-5.5-2(b)(2), of the Act. Such claims caused actual damages to the State.

81. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 5-11-5.5-2(b)(8), of the Act. Such claims caused actual damages to the State.

COUNT XI

VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW LA. REV. STAT. § 46:438.3 *et seq.*

82. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

83. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 46:438.3(A) of the Act. Such claims caused actual damages to the State.

84. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 46:438.3(B) of the Act. Such claims caused actual damages to the State.

COUNT XII

VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT MD. CODE ANN., HEALTH-GEN §§2-602 *et seq.*

85. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

86. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 2-602(A)(1), of the Act. Such claims caused actual damages to the State.

87. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 2-602(A)(2), of the Act. Such claims caused actual damages to the State.

COUNT XIII

VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS ACT MASS. ANN. LAWS. CH. 12, §§ 5B *et seq.*

88. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

89. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 5B(1), of the Act. Such claims caused actual damages to the State.

90. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 5B(2), of the Act. Such claims caused actual damages to the State.

COUNT XIV

VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT MCLS §§ 400.607 *et seq.*

91. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

92. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 400.607(1), of the Act. Such claims caused actual damages to the State.

93. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 400.607(3), of the Act. Such claims caused actual damages to the State.

COUNT XV

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT MINN. STAT. §15C.02 *et seq.*

94. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

95. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 15C.02(a)(1), of the Act. Such claims caused actual damages to the State.

96. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 15C.01(a)(2), of the Act. Such claims caused actual damages to the State.

COUNT XVI

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT MONT. CODE ANN. 17-8-403(1) *et seq.*

97. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

98. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 17-8-403(1)(a), of the Act. Such claims caused actual damages to the State.

99. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 17-8-403(1)(b) of the Act. Such claims caused actual damages to the State.

COUNT XVII

VIOLATIONS OF THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT NEV. REV. STAT. §§ 357.040 *et seq.*

100. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

101. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 357.040(1)(a), of the Act. Such claims caused actual damages to the State.

102. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 357.040(1)(b), of the Act. Such claims caused actual damages to the State.

COUNT XVIII

VIOLATIONS OF THE NEW HAMPSHIRE FALSE CLAIMS ACT N.H. REV. STAT. ANN. §167:61-b *et seq.*

103. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

104. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 167:61-b(I)(a), of the Act. Such claims caused actual damages to the State.

105. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 167:61-b(I)(b), of the Act. Such claims caused actual damages to the State.

COUNT XIX

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT N.J. STAT. §2A:32C-3 *et seq.*

106. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

107. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 2A:32C-3(a), of the Act. Such claims caused actual damages to the State.

108. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 2A:32C-3(b), of the Act. Such claims caused actual damages to the State.

COUNT XX

VIOLATIONS OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT N.M. STAT. ANN. § 27-14-4A *et seq.*

109. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

110. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 27-14-A(1), of the Act. Such claims caused actual damages to the State.

111. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 27-14-4A(2), of the Act. Such claims caused actual damages to the State.

COUNT XXI

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT NY CLS ST. FIN. § 189 *et seq.*

112. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

113. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 189(1)(a), of the Act. Such claims caused actual damages to the State.

114. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 189(1)(b), of the Act. Such claims caused actual damages to the State.

COUNT XXII

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT N.C. GEN. STAT. §1-607(A) *et seq.*

115. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

116. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 1-607(A)(1), of the Act. Such claims caused actual damages to the State.

117. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 1-607(A)(2), of the Act. Such claims caused actual damages to the State.

COUNT XXIII

VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT OKLA. STAT. TIT. 63, §5053.1B *et seq.*

118. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

119. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 5053.1B(1), of the Act. Such claims caused actual damages to the State.

120. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 5053.1B(2), of the Act. Such claims caused actual damages to the State.

COUNT XXIV

VIOLATIONS OF THE RHODE ISLAND FALSE CLAIMS ACT R.I. GEN. LAWS §9-1.1-3 *et seq.*

121. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

122. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 9-1.1-3(a)(1), of the Act. Such claims caused actual damages to the State.

123. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 9-1.1-3(a)(2), of the Act. Such claims caused actual damages to the State.

COUNT XXV

VIOLATIONS OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT TENN. CODE ANN. §§ 71-5-182(a) *et seq.*

124. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

125. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 71-5-182(a)(1)(A), of the Act. Such claims caused actual damages to the State.

126. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 71-5-182(a)(1)(B), of the Act. Such claims caused actual damages to the State.

COUNT XXVI

VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION ACT TEX. HUM. RES. CODE ANN. §36.002 *et seq.*

127. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

128. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 36.002(1), of the Act. Such claims caused actual damages to the State.

129. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 36.002(4), of the Act. Such claims caused actual damages to the State.

COUNT XXVII

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT VA. CODE §§ 8.01-216.3A *et seq.*

130. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

131. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 8.01-216.3A(1), of the Act. Such claims caused actual damages to the State.

132. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 8.01-216.3A(2), of the Act. Such claims caused actual damages to the State.

COUNT XXVIII

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT WIS. STAT. §20.931(2) *et seq.*[2]

133. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

134. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section 20.931(2)(a), of the Act. Such claims caused actual damages to the State.

[2] The Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§ 20.931 *et seq*. was repealed effective July 15, 2015. Relator seeks only damages resulting from Defendants' conduct prior to that date.

135. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section 20.931(2)(b), of the Act. Such claims caused actual damages to the State.

COUNT XXIX

VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT
Colorado Stat. §§25.5-4-304 - 25.5-4-310

136. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

137. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Section §§25.5-4-304 - 25.5-4-310 of the Act. Such claims caused actual damages to the State.

138. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Section §§25.5-4-304 - 25.5-4-310 of the Act. Such claims caused actual damages to the State.

COUNT XXX

VIOLATIONS OF THE ALASKA MEDICAL ASSISTANCE FALSE CLAIMS REPORTING ACT
AK Stat § 09.58.010 *et seq.*

139. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

140. Through these acts, the Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment to the State in violation of Sec. 09.58.010(a)(1) of the Act. Such claims caused actual damages to the State.

141. Through these acts, the Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim to the State, in violation of Sec. 09.58.010(a)(2) of the Act. Such claims caused actual damages to the State.

COUNT XXXI

VIOLATIONS OF THE CALIFORNIA INSURANCE FRAUD PREVENTION ACT
Ins. Code §§ 1871 *et seq.*

142. Relator re-alleges and incorporates by reference each and every allegation contained in the paragraphs above as though fully set forth herein.

143. Through these acts, Defendants knowingly submitted false claims for payment to private insurance companies throughout California in violation of Ins. Code § 1871.7(b). Such claims have damaged private insurance companies throughout the State of California.

PRAYER

WHEREFORE, Relator, on behalf of the United States, respectfully requests that:

a. This Court enter an order determining that Defendants violated the FCA by making false statements and records to cause false claims to be submitted to the United States;

b. This Court enter an order requiring Defendants to pay the maximum civil penalties allowable to be imposed for each false or fraudulent claim presented to the United States;

c. This Court enter an order requiring Defendants to cease and desist from violating the FCA;

d. This Court enter an order requiring Defendant to pay all expenses, attorneys' fees and costs associated with this action;

e. This Court enter an order paying Relator the maximum statutory award for its contributions to the prosecution of this action; and

f. Any and all other relief as this Court determines to be reasonable and just.

PLAINTIFF/RELATOR DEMANDS A TRIAL BY JURY ON ALL COUNTS

Dated: September 6, 2019

Respectfully submitted,

/s/ Timothy M. Holly

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